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510(K) Summary

Summary of 510(K) safety and effectiveness information upon which the substantial equivalence determination is based:

Prepared: June 12, 2008

Applicant: John Riccio (Fusion Medical)
1663 South Main St
Waterbury, CT 06706

MAY 20 2009

Telephone: 203-823-8511
Fax: 860- 454-7562
Contact: John Riccio

Device Name:	Subtalar Arthrorisis Implant
Device Trade Name:	STI (Subtalar implant)
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number:	888.3040
Product Code:	87 HWC
Predicate Devices:	K031155- Osteomed Subtalar Implant K0322902-(Nexa) Futura Subtalar Implant

Device Description:

The Fusion Medical STI (Subtalar Implant) is a one-piece device made of titanium (6AL-4V ELI) intended to be implanted into the sinus tarsi of the foot. The implant will be available in 5 sizes, 8mm-12mm diameters. The implant that is used in the treatment of excess motion of the talus relative to the calcaneus acts as a spacer for the joint, maintaining the joint space, allowing for range of motion, but limiting excessive pronation.

Indication for Use:

The Fusion Medical STI (Subtalar Implant) is intended to treat hyperpronation of the foot and stabilize the subtalar joint. It is intended to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and resulting sequela.

Example are:

Subtalar instability	Tarsal Coalitions
Painful flat foot	posterior tibial tendon deformity
Congenital flat foot	Flat foot treatment in children and adolescent
Paralytic Flat foot	

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Comparison to Predicate Device:

The legally marketed predicate device to which this device is substantially equivalent is the Futura CSI 510(k) K032902.

Regulatory Class: II
Product Code: 87 HWC

Table 1. Comparison of Fusion Medical STI and Futura Biomedical Subtalar Implant

Item	Fusion	Futura
Product Name:	STI Subtalar Implant	Subtalar Arthrorisis Implant
Use:	Single Use	Single Use
Fixation:	Screw	Screw
Constraint:	Non Constrained	Non Constrained
Material:	Titanium 6AL-4V ELI	Titanium 6AL-4V ELI
Sizes:	5	6
Indications	The Fusion Medical STI implant is intended to treat hyperpronated foot and stabilize the subtalar joint. It is intended to treat forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronaton and resulting in sequela.	The Futura Subtalar arthrorisis implant is intended to treat hyreppronated foot and stabilize the subtalar joint. It is intended to forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion, but blocking excessive pronation and resulting in sequela.
	Examples Include:	
	Congenital flat foot	Congenital flat foot
	Tarsal coalition	Tarsal coalition
	Painful flat foot	Painful flat foot
	Posterior tibial tendon dysfunction	Posterior tibila tendon dysfunction
	Paralytic flat foot.	Paralytic flat foot
	Subtalar instability	Subtalar instability
	Foot treatment of adult and children (Flat Foot)	Foot treatment of adult and children (Flat Foot)

Similarities of the Fusion Medical STI (Subtalar Implant) and Nexas Futura CSI Implant include the following:

Both devices are intended for surgical implantation longer than 30 days. No new materials are introduced in either product. Both devices are made of industry standard materials. Both devices are placed into the sinus tarsi of the foot, allowing normal subtalar joint motion while blocking excessive pronaton and resulting in sequela. Both devices are similar in size; They have the same indications of use.

Summary:

The Fusion Medical STI and the (Nexa) Future CSI, have the same indications of use. The design of the STI (Fusion Medical) and The CSI (Nexa) are comparable. The New Fusion Medical STI implant is substantially equivalent to the predicate device currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 2009

Fusion Medical
% Mr. John Riccio
1663 South Main Street
Waterbury, Connecticut 06706

Re: K081755
Trade/Device Name: Fusion Medical STI System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: May 4, 2009
Received: May 4, 2009

Dear Mr. Riccio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

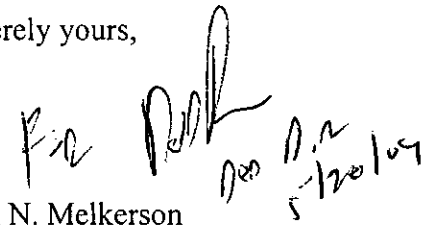
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at

(240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081755

Device Name: Fusion Medical STI System

Indications for Use:

The Fusion Medical STI is intended to treat hyperpronated foot, and stabilize the subtalar joint. It is intended to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion, but blocking excessive pronation and resulting sequela.

Examples are:

Subtalar instability, painful flat foot, congenital flat foot, paralytic flat foot, tarsal coalitions, posterior tibial tendon deformity and flat foot treatment in children and adolescents.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K081755